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6 IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

7 JEREMY OLSEN,

8 Plaintiff,

9 v.

10 XAVIER BECERRA, in his official
11 capacity as Secretary of the United
States Department of Health and Human
12 Services,

13 Defendant

No. 2:21-cv-00326-SMJ

MOTION FOR PRELIMINARY
INJUNCTION

March 18, 2022
With Oral Argument: 1:45 P.M.
Thomas S. Foley United States
Courthouse

1 Pursuant to FED.R.CIV.P. 65, Plaintiff Jeremy Olsen moves for a
2 preliminary injunction barring the Secretary from continuing to reject continuous
3 glucose monitor (CGM) claims based on CMS 1682-R and/or the claim that a
4 CGM is not “primarily and customarily used to serve a medical purpose.” The
5 Secretary’s underlying position on which the claim denials in this case are based
6 is in “bad faith” as this Court found in April. *See Olsen v. Becerra*, 2021 WL
7 3683360 (E.D. Wash. April 20, 2021) (“Defendant’s conduct meets the ‘high-
8 threshold’ for an award of bad-faith fees.”) (cleaned up). Beyond that, the
9 repeated denials and delay demonstrate a deliberate indifference to human life and
10 suffering.

11 Even after this Court’s “bad faith” finding, the Secretary continued to reject
12 CGM claims, including claims by Mr. Olsen, on the “bad faith” grounds.
13 Likewise, one aspect of this Court’s “bad faith” finding was the Secretary’s failure
14 to file the administrative record as required by the statute and subsequent failure
15 to comply with this Court’s Order to do so. That conduct caused additional delay
16 and this Court characterized the conduct as “vexatious.” Incredibly, the Secretary
17 has chosen to repeat that conduct and failed to file the administrative record with
18 the Answer as required by 42 U.S.C. § 405(g). Because no administrative record
19 is on file, Mr. Olsen is filing a motion for a preliminary injunction rather than a
20 motion for summary judgment.

1 Based on information produced by the Secretary, it is believed that ~13,000
2 claims are denied on the bad faith/illegal grounds each month. A preliminary
3 injunction will prevent tens of thousands of persons (including Mr. Olsen) from
4 continuing to suffer from the Secretary's bad faith conduct.

5 I. BACKGROUND

6 A. FACTUAL BACKGROUND

7 As described in the attached declaration of Dr. Argento, diabetics
8 (particularly Type I, "brittle" diabetics who also suffer from unawareness) are in
9 danger of suffering from severe hypoglycemic events. These events, in both the
10 short and long term, cause irreparable injury in the form of injury to various
11 systems of the body. If not treated, in the short term, these events can lead to
12 death. In the long term, cumulatively, these events can lead to blindness, nerve
13 damage leading to loss of limbs, kidney damage, and reduced cognitive function.
14 One purpose of a CGM is to avoid these events by alerting users to out of range
15 glucose values and, when combined with an insulin pump, controlling dispensed
16 insulin.

17 Without prior notice and comment, on January 12, 2017, the Secretary
18 issued CMS Ruling 1682-R. *See* Exhibit A; Pistorino Declaration. There, the
19 Secretary maintained that any CGM which did not completely replace finger
20 sticks was "precautionary" and not covered. *Id.* The Secretary asserted that if
the reading from a CGM sensor had to be confirmed with a fingerstick prior to

1 making a treatment decision, the CGM was not "primarily and customarily used
2 to serve a medical purpose." *Id.*

3 Conversely, CGMs which do replace finger sticks the Secretary labeled
4 "therapeutic" and considered covered. By its own terms, CMS 1682-R was
5 effective as of the very date it issued – *i.e.*, January 12, 2017. *Id.* Pursuant to 42
6 C.F.R. § 405.1063, ALJs and the Medicare Appeals Council are bound by CMS
7 Rulings and must apply them. Thus, any claim with a date of service after
8 January 12, 2017, which does not match CMS 1682-R's definition of
9 "therapeutic" must be rejected.

10 On November 4, 2020, the Secretary published a notice of proposed rule
11 making to withdraw CMS 1682-R and cover CGMs. As published, the proposed
12 change was supposed to go into effect on April 1, 2021. However, the Secretary
13 never issued a notice of final rule making and continued to reject claims based on
14 CMS 1682-R. On December 28, 2021, the Secretary published another notice of
15 final rule making with regard to CGMs. Importantly, the proposed new Rule only
16 applies to claims with dates of service after February 28, 2022. Further, because
17 Medicare insureds have one year to submit claims (which they may need to collect
18 claims to meet amount-in-controversy requirements), the Secretary's publication
19 implicitly indicates his intention to apply the bad faith, illegal Ruling for another
20 year.

Approximately half of those on Medicare have annual incomes of less than \$30,000 and one quarter of Medicare enrollees (such as Mr. Olsen) have annual incomes of less than \$17,000.¹ As shown in the denials of Mr. Olsen's claims a 90-day supply of CGM sensors costs ~\$1,500 for a yearly cost of ~\$6,000.

B. LEGAL BACKGROUND

1. Medicare's Notice and Comment Requirements

Pursuant to 42 U.S.C. § 1395hh(a)(2):

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

The "paragraph (1)" referred to requires the Secretary to issue such rules, requirements or other statements of policy in the form of regulations.

Pursuant to 42 U.S.C. § 1395hh(b)/(c), proposed regulations must be published in the FEDERAL REGISTER and the public provided no less than 60 days to comment on the proposed regulations before the regulations may be published as final regulations.

In *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019), the Supreme

¹ <https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/>

1 Court held that the Medicare specific notice and comment provisions (rather than
 2 the APA's notice and comment provisions) apply to Medicare. *Id.* at 1809. Two
 3 differences between notice and comment under the Medicare Act and under the
 4 APA are: 1) the substantive/interpretive distinction under the APA does not apply
 5 to the Medicare Act; and 2) the Medicare Act requires 60 days of notice and
 6 comment rather than the 30 days under the APA. Thus, under § 1395hh, no rule,
 7 requirement, or statement of policy that establishes or changes the standard for
 8 paying for services/benefits can take effect until the notice and comment
 9 provisions have been complied with.

10 **2. Preliminary Injunctions**

11 To obtain relief, a party seeking a preliminary injunction must show that:
 12 1) they are “likely to succeed on the merits”; 2) they are “likely to suffer
 13 irreparable harm in the absence of preliminary relief”; 3) “the balance of equities
 14 is in their favor”; and 4) “an injunction is in the public interest.” *See, e.g., Disney*
 15 *Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (cleaned up).
 16 These are evaluated on a sliding scale in which elements are “balanced so that a
 17 stronger showing of one element may offset a weaker showing of another.”
 18 *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017). Where the federal
 19 government is the opposing party, the balance of equities and the public interest
 20 merge. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

Pursuant to FED.R.CIV.P. 65(c), “security in an amount that the court considers proper” may be required for the issuance of a preliminary injunction. The Rule has been read to vest broad discretion in the district court to determine the amount of the injunction bond, including not requiring any bond at all. *See, e.g., Barahona-Gomez v. Reno*, 167 F.3d 1228, 1237 (9th Cir. 1999); *Swanson v. Univ. of Hawaii Prof. Assembly*, 269 F.Supp.2d 1252 (D. Hawaii 2003) (waiving bond requirement based, in part, on plaintiff’s financial resources). Further, the Court may dispense with a bond when it concludes there is no realistic likelihood of harm to the defendant from enjoining his conduct. *See Johnson v. Couturier*, 572 F.3d 1067, 1086 (9th Cir. 2009).

II. DISCUSSION

A. Mr. Olsen Is Likely to Succeed on the Merits

The causes of action in this case can be divided into two groups: 1) causes of action that go directly to the Secretary’s denial of CGM claims on the grounds that a CGM is not “primarily and customarily used to serve a medical purpose”; and 2) Cause of Action V that goes to the illegal issuance of CMS 1682-R codifying the not “primarily and customarily used to serve a medical purpose” policy on which all claims since January 12, 2017 have been denied.

1. “Primarily and Customarily Used to Serve a Medical Purpose” Causes of Action

All the causes of action (except Cause of Action IV and VI) in this case are

1 founded on the Secretary's rejection of CGM claims on the grounds that CGMs
2 are not "durable medical equipment" (42 U.S.C. § 1935x(n)) because CGMs are
3 not "primarily and customarily used to serve a medical purpose" (42 C.F.R. §
4 414.202). The causes of action assert that there is not substantial evidence to
5 support the Secretary's position, it is arbitrary and capricious, etc.

6 There is not now nor has there ever been any good faith basis for the Secretary's
7 position. Outside bad faith/frivolous rejections and litigation delay tactics
8 founded on the same, no rational person could ever conclude that a CGM is not
9 "primarily and customarily used to serve a medical purpose." As noted above,
10 this Court has previously determined that the Secretary's conduct in this regard is
11 "groundless" and in "bad faith."

12 **2. Cause of Action IV**

13 This cause of action goes to whether CMS 1682-R issued in compliance
14 with the Medicare Act's specific notice and comment provisions (42 U.S.C. §
15 1395hh). Without prior notice and comment (including publication in the
16 FEDERAL REGISTER), CMS 1682-R issued on January 12, 2017, effective as of that
17 very day. That was a violation of 42 U.S.C. § 1395hh. As stated in § 1395hh(2),
18 "[n]o rule, requirement, or other statement of policy" that establishes or changes
19 a standard concerning the scope of benefits, payment for services, etc. shall take
20 effect unless promulgated by regulation issued in accordance with the notice and

comment provisions. On its face, CMS 1682-R describes itself, *inter alia*, as a "statement[] of policy and interpretation." Exhibit A at 1. Further, of course, by setting forth the standard of "precautionary" and "therapeutic" CGMs, CMS 1682-R purports to establish or change the standard concerning the scope of benefits, payment for services, or eligibility of individuals receiving a CGM. Thus, under § 1395hh, CMS 1682-R cannot "take effect unless it is promulgated by the Secretary by regulation" (including compliance with the notice and comment provisions).

Here, there is no genuine issue of material fact that the Secretary did not comply with the notice and comment provisions. Nothing was published in the FEDERAL REGISTER concerning proposed regulations, there was no opportunity for the public to comment, and there was no publication of final regulations. *See* 42 U.S.C. § 1395hh(b). Instead, in defiance of the statute, the Secretary simply issued a ruling establishing a new standard for benefits and, relying on that illegal standard, proceeded to reject claims (including Mr. Olsen's). *See* AR974 ("We, like the ALJs, are bound by CMS Rulings.", *citing* 42 C.F.R. § 405.1063(b)). Thus, CMS 1682-R issued in violation of the law.

B. Olsen Will Suffer Irreparable Harm in the Absence of Preliminary Relief

Of course, the ultimate irreparable harm is death. As set forth in the attached declaration, the very purpose of a CGM is to prevent the injuries and

1 death associated with uncontrolled diabetes. Further, as shown, absent Medicare
2 coverage, a very large portion of the Medicare beneficiaries (including Mr. Olsen)
3 would simply not be able to afford a CGM and, therefore, would suffer the
4 irreparable harms associated with not having a CGM (*e.g.*, death, blindness, loss
5 of limbs, cognitive decline).

6 **C. The Balance of Equities Favors Mr. Olsen and an**
7 **Injunction is in the Public Interest**

8 As noted above, where the federal government is the opposing party, the
9 balance of equities and the public interest merge. *Nken*, 556 U.S. at 435. In this
10 case, Mr. Olsen and the public have an interest in the laws passed by Congress
11 being enforced. In addition, Mr. Olsen and the public have an interest in
12 regulations adopted in accordance with the law being enforced. In addition, Mr.
13 Olsen has an interest in continuing to live and avoiding the permanent physical
14 damage that results from each diabetic event. Thus, Mr. Olsen has an interest in
15 not going blind, keeping all of his limbs, etc.

16 The Secretary can have no legitimate interest in acting unlawfully or in “bad
17 faith.” Further, in light of the fact that the Secretary has published his intention
18 to apply a different rule for claims with dates of service after February 28, 2022,
19 the requested relief would simply order the Secretary to apply that same rule
20 earlier. Further, the sought after injunction will not require that claims are
approved – it will merely preclude the Secretary from denying claims on “bad

1 faith"/illegal grounds. Thus, the balance of equities favor of Mr. Olsen and an
2 injunction is in the public interest.

3 **D. No Bond Should Be Required**

4 As noted above, this Court has discretion to set the bond at any amount,
5 including requiring no bond at all. No bond should be required in this case.

6 The purpose of a bond is to compensate the enjoined party for harm if it is
7 later determined that the injunction was improvidently granted. As an initial
8 matter, no harm to the government would be associated with entry of the
9 injunction. The injunction would not require approval of claims – it would merely
10 preclude denial of claims on “bad faith”/illegal grounds. Thus, there is no harm
11 to offset and no bond is needed. In any event, Mr. Olsen is of very limited means
12 and no bond should be required. Finally, no bond should be required to preclude
13 the Secretary from engaging in conduct that has already been determined to be in
14 “bad faith.”

15 **CONCLUSION**

16 For the reasons set forth above, this Court should enter an injunction as
17 requested.

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19 Respectfully submitted this 8th day of February, 2022.
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PARRISH LAW OFFICES

By: /s/ James C. Pistorino
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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury under the laws of the state of Washington that on the date below, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

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DATED this 8th day of February, 2022, at Seattle, Washington.

s/ Julia Wolfe
Julia Wolfe, Legal Assistant